

**Institutional Review Board**

**Protocol Violation Report Form**

*Human Research & Compliance*

LOMA LINDA UNIVERSITY HEALTH | Office of the Vice President of Research Affairs

 24887 Taylor Street, Suite 202 Loma Linda, CA 92350

*(909) 558-4531 (voice)*

IRB #:

Principal Investigator:

Title of protocol:

Sponsor (if applicable):

Any departure from the IRB-approved research protocol without prior IRB approval is considered to be a Protocol Violation unless done for the health or safety of research subjects. Upon becoming aware of a possible Protocol Violation, the Principal Investigator should use this Report Form to make a preliminary determination whether the event is or may be a Protocol Violation that should be promptly reported to the IRB.

1. **Determine if event is a Serious Protocol Violation.** Does the event adversely affect any of the following:
* Rights/welfare of subjects
* Safety of subjects
* Benefits to subjects
* Integrity of research data
* Subject’s willingness to continue participation

If you are uncertain, report the event to the IRB for further guidance.

If the event adversely affects any of the preceding items, complete the remaining report within 5 working days of becoming aware of the circumstances and submit to the IRB. (See the [IRB Tip on Examples of Serious or Minor Protocol Violations](http://www.llu.edu/assets/research-affairs/docs/irb-primers-and-tips-examples-of-serious-or-minor-violations.docx)).

If the event does NOT adversely affect any of the preceding items, STOP and do NOT proceed further on this report. The event is NOT a Serious Protocol Violation and need NOT be reported promptly to the IRB at this time. Principal Investigators should record all minor events in a simple spreadsheet (see sample “[Minor Protocol Violation Log](http://www.llu.edu/assets/research-affairs/docs/irb-minor-protocol-violation-log.xlsx)”) and submit the accumulated report as an attachment to the study’s Research Report at the end of the IRB approval period (i.e., for continuing review approval or termination of the study).

1. **Report Serious Protocol Violation**
2. Date of violation:
3. Date PI became aware of violation:

NOTE: If more than 5 working days have passed since the date you became aware of the violation, explain the delay in reporting:

1. Describe the specific violation(s) and why/how it occurred:
2. Describe actions taken to address the violation(s), prevent recurrence, and ensure subject safety:
3. **Report Pattern of Minor Violations** A pattern of minor violations may together adversely affect one or more of the criteria listed in I above and thus may constitute a serious violation. Within 5 days of recognizing this pattern, the PI should report it.
4. Attach Minor Protocol Violation Log.
5. Describe actions taken to address the violation(s), prevent recurrence, and ensure subject safety:

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Principal Investigator Date

*IRB OFFICE USE ONLY*

**ACKNOWLEDGEMENT and REPORT TO PRINCIPAL INVESTIGATOR**

[ ]  Serious Violation Report is accepted as submitted, no further action required.

[ ]  This is classified as a minor protocol violation. Record this event in the “[Minor Protocol Violation Log](http://www.llu.edu/assets/research-affairs/docs/irb-minor-protocol-violation-log.xlsx)” and submit with renewal request or upon study termination.

[ ]  Further information required from investigator, as follows:

[ ]  PI needs consultation with IRB Chair. (Contact HRC at ext. 44531)

[ ]  Violation will be reported the Full Board for review.

[ ]  Violation Report referred to Research Compliance regarding \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Study must be immediately suspended. Full Board review is required.

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 IRB Chair or Designee Date

cc: Manager, Research Compliance